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100TH CONGRESS *2d Session* | SENATE | REPORT 100-303

PRESCRIPTION DRUG MARKETING ACT OF 1987

MARCH 18, 1988.—Ordered to be printed

Mr. BENTSEN, from the Committee on Finance, submitted the following

REPORT

[To accompany H.R. 1207]

The Committee on Finance, to which was referred the bill (H.R. 1207) to amend the Federal Food, Drug, and Cosmetic Act to ban the reimportation of drugs produced in the United States, to place restrictions on the distribution of drug samples, to ban certain resales of drugs by hospitals and other health care facilities, and for other purposes, having considered the same reports favorably thereon and recommends that the bill do pass.

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I. SUMMARY

H.R. 1207 makes changes in the national drug distribution system. The bill prohibits the reimportation of prescription drugs except by the manufacturer or for emergency use, bans the sale, trade or purchase of drug samples, prohibits with certain exceptions the resale of prescription drugs purchased by health care entities for their own use, mandates storage, handling and accounting requirements for drug samples, prohibits the wholesale distribution of drugs in interstate commerce from states which do not license wholesalers or whose licensing requirements do not meet minimum

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standards, and establishes a range of criminal and civil penalties for violations of these provisions.

The purpose of the legislation is to curb operation of the diversion market for prescription drugs that operates outside of normal channels of distribution and makes it difficult to protect American consumers from mislabeled, subpotent, adulterated, expired, or counterfeit pharmaceuticals.

II. Committee Action on the Bill

The Senate counterpart to H.R. 1207, S. 368, was introduced on January 21, 1987, and was referred to the Committee on Finance. Hearings on that bill were held before the Subcommittee on International Trade on June 15, 1987. Following passage of H.R. 1207 by the House of Representatives on May 4, 1987, that bill also was referred to the Committee on Finance.

III. General Explanation

A significant volume of pharmaceuticals is being reimported to the United States as American Goods Returned. These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. Moreover, the hazards associated with reimports have forced the Food and Drug Administration and the U.S. Customs Service to spend inspectional and other resources that are sorely needed in other areas.

The distribution of drug samples to patients by practitioners licensed to dispense pharmaceuticals is a useful and valuable medical tool. The bill is designed to retain the positive benefits of samples while providing for improved storage and handling, greater accountability and strong penalties for unauthorized distribution.

The resale of prescription drugs by health care entities to persons outside the corporate umbrella of the institution—such as a wholesaler—helps fuel the diversion market, and, with certain exceptions, is prohibited by this bill.

SECTION 1—SHORT TITLE

Subsection (a) provides that the Act may be cited as the "Prescription Drug Marketing Act of 1987." Subsection (b) provides that all amendments or repeals are to the Federal Food, Drug and Cosmetic Act (FDCA).

SECTION 2—FINDINGS

This section contains findings regarding the threat to the public health posed by prescription drug diversion and counterfeiting. These findings form the basis for amending the FDCA to ensure the safety and efficacy of the prescription drug supply of the United States by restricting or prohibiting certain distribution practices.

SECTION 3—REIMPORTATION

This section amends Section 801 of the FDCA to prohibit the reimportation of U.S.-produced pharmaceuticals except by the man-

ufacturer of the product or as authorized by the Secretary of Health and Human Services for emergency purposes.

Reimported pharmaceuticals threaten the American public health in two ways. First, foreign counterfeits, falsely described as reimported U.S.-produced drugs, have entered the distribution system. Second, proper storage and handling of legitimate pharmaceuticals cannot be guaranteed by U.S. law once the drugs have left the boundaries of the United States.

A broad exception has been made for pharmaceuticals returned to the manufacturer from abroad. This exception is necessary to avoid interference with usual and customary business practice by assuring that pharmaceuticals which have been recalled or damaged or otherwise become unsuitable for distribution to consumers will be returned to the original manufacturer.

A limited exception is also provided for the Secretary of Health and Human Services to authorize reimportations, on a case-by-case basis, of pharmaceuticals needed for emergency medical care.

SECTION 4—SALES RESTRICTIONS

This section amends Section 503 [21 USC 353] of the FDCA to create a new subsection (c) which prohibits the selling, purchasing, trading or offer to sell, purchase or trade a drug sample. It also prohibits resales and trades by hospitals and other health care entities of pharmaceuticals except under certain circumstances. Resale and trade does not include the withdrawal from the market for credit or exchange of any drugs in the event of a recall by a manufacturer where the manufacturer has notified the Secretary of Health and Human Services of the recall.

In order for a drug sample to be resold to an ultimate consumer, it must be removed from its packaging and often physically adulterated to remove the "sample" designation from the pill or capsule. Recalls become impossible and outdated pharmaceuticals have been commingled with adulterated samples. Section 503(c)(1) would make the sale, purchase or trade of drug samples, or the offer to sell, purchase or trade drug samples *per se* illegal.

The term "sample" is defined as a unit of a drug, subject to subsection (b), which is not intended to be sold and, in fact, is intended to promote the sale of the drug. Pharmaceutical manufacturers and distributors have had a long established practice of providing samples of their prescription drugs to physicians and other practitioners licensed to prescribe such drugs who, in turn, provide them to their patients. The purpose is to acquaint the practitioner with the therapeutic value of the medication and thus encourage the written prescription of the drug. Samples are usually, though not always, packaged differently than regular stock packages sold to retail pharmacies, often in smaller dosages and/or in packaging clearly marked with the word "sample" or some equivalent statement. In no case would a sample include drugs provided physicians or other licensed practitioners for investigational use under Section 505(i) of the FDCA. Of course, the distribution must be in strict conformance with the FDA's IND regulations in order for the drug to qualify as one for investigational use.

In Section 7, violation of this provision is made a felony punishable by up to 10 years in prison or a fine of up to $250,000 or both. The Pharmaceutical Manufacturers Association has expressed concern that under the *Park* doctrine [1] officers or executives of their member firms might face criminal liability involving these severe penalties merely because one of their sales representatives was convicted of purchasing, selling or trading, or offering to purchase, sell or trade drug samples. To allay this concern, the following sentence in 503(c)(1) states, "Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase or trade in violation of this paragraph by other employees of the manufacturer or distributor."

The Committee does not mean to imply that a correct reading of *U.S.* v. *Park* would confer criminal liability on the officers of executive of any company solely because of the violative behavior of other employees of the company.

Paragraph (c)(2) was included to deter the abuse of coupons, which are not themselves samples but which may be exchanged for a sample dosage of regular pharmaceuticals from a pharmacy when accompanied by a valid prescription. Trafficking in or counterfeiting of coupons would be prohibited.

Section 503(c)(3) would prohibit resales of pharmaceuticals by hospitals and other health care entities or charitable organizations with certain exceptions. This provision is intended to cover resales by both for-profit and nonprofit health care entities. These institutions typically receive discount prices, substantially below the average wholesale price (AWP) for pharmaceuticals, based on their status as a health care entity or charity. When hospitals or other health care entities obtain pharmaceuticals at favorable prices and then resell those drugs at a profit, they are unfairly competing with wholesalers and retailers who cannot obtain such a favorable price. Such resales may defraud manufacturers, who are led to believe that the drugs are for the use of the health care entity. In any case, these resales reward the unscrupulous and penalize the otherwise honest and efficient wholesaler or retailer while fueling the diversion market.

Several important exceptions to the resale ban are provided for in 503(3)(B) to allow for legitimate commercial activity and the provision of health care to patients. The purchase or acquisition of pharmaceuticals by a health care entity that is a member of a group purchasing organization is allowed, as are transfers between members of the organization. The same exception applies to health care entities that are under common control. A charitable institution as described in section 501(c)(3) of the Internal Revenue Code of 1954 is permitted to sell or transfer pharmaceuticals to a nonprofit affiliate to the extent otherwise permitted by law.

Health care entities can dispense drugs to their patients pursuant to a valid prescription. This section contains a general exception for emergency medical reasons, which include transfers between health care entities that may have temporarily run out of a

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[1] *United States* v. *Park*, 421 US 658 (1975).

drug, and even transfers from health care entities to retail pharmacies. This exemption was provided so that, for example, hospitals might act as suppliers of last resort to community pharmacies in rural areas. It is intended to cover the situation in which a pharmacy runs out of a medication needed to fill a prescription and needs to borrow a stock package from the hospital pharmacy and replace it when the drug is received from its regular distribution source.

Health care entities are defined for the purpose of section 503(3)(A) to exclude wholesale distributors or retail pharmacies.

Section 4 of the bill is not intended to limit nonremunerative transfers of prescription drugs from a group model health maintenance organization (HMO) to a contracting physician or group of contracting physicians for dispensing in the course of treatment of patients.

Group model HMOs generally contract with a physician group practice, usually on a capitation basis, to provide health care services to the HMO members. Typically, the HMO or its hospital purchases prescription drugs for use in the treatment of the physician group's patients. In some cases, those drugs may be transferred physically without charge or cost to physicians in the group practice for dispensing in the course of treatment of individual patients. Any revenue derived from dispensing the drugs is revenue of the HMO. This section is not intended to affect these practices.

SECTION 5—DISTRIBUTION OF SAMPLES

This section amends section 503 of the FDCA by adding subsection 503(d). It establishes conditions with which a manufacturer or distributor must comply in order to be qualified to distribute samples to licensed practitioners. This section permits samples to be distributed by either of two systems. One system involves use of the mail or common carrier and the other is the physical distribution by company respresentatives. Coupons, which are not samples, are an alternative means of providing sample doses and are not subject to 503(d) restrictions.

Drug samples may only be distributed to practitioners licensed or authorized by state law to prescribe such drugs. If the practitioner requests, the samples may be distributed to the pharmacy of a hospital, clinic, or other health institution with which the practitioner is affiliated.

To receive samples, practitioners are required by subsections (d)(2)(B) and (d)(3)(A) to sign a request form which contains the practitioner's name, address, professional designation, type and quantity of drug sample, name of the manufacturer or distributor of the drug sample and the date. With regard to the identity of the drug sample, manufacturers or distributors could comply with this requirement either through a written description or a unique numerical code designating the product name, strength and number of units per package. However, if such a code designation is used, the code must be clearly translated on the form itself so that the licensed practitioner is fully aware of the product, strength and quantity he is requesting by affixing his signature to the request form.

It is the Committee's intent that such a request must be made each time a physician wants samples. A standing written request from a physician for samples to be distributed periodically would not satisfy the requirements of this provision; except that FDA may provide by regulation for the delivery of standing orders by mail covering small numbers of samples for strictly limited periods of time.

Under the bill, manufacturers or distributors will be free to use outside contractors, such as mail-order houses, to handle the distribution.

For those manufacturers or distributors who choose to use the mail or common carrier method of sample distribution, section 503(d)(2)(A)(ii) requires that they establish a system which requires a written receipt from the practitioner, or a responsible person in the office of the practitioner, confirming the fact of delivery. Section 503(d)(2)(C) requires manufacturers or distributors to maintain the request and receipt forms and to maintain records which would identify the drug distributed and the recipients of the distribution for a period of three years.

Section 503(d)(3) sets forth the conditions under which manufacturers or distributors may employ their representatives to physically deliver drug samples to practitioners. The recordkeeping requirements described in subparagraph 503(d)(3)(C) are an essential component of the overall sample control system.

The manufacturers or distributors which choose to distribute samples by mail or common carrier, and hence are not subject to civil penalties for the diversion of drug samples by their employees, are specifically required by section 503(d)(2)(C) to make the forms, receipts and records associated with the distribution of drug samples available to all Federal and state officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

Section 503(d)(3)(D) requires the reporting of any significant loss and all known thefts of drug samples. No obligation to investigate beyond that required in other sections of the bill is implied by this paragraph. Moreover, a discrepancy is not a theft unless it is known to be a theft.

Subparagraph 503(d)(3)(E) requires drug manufacturers or distributors to notify the Secretary whenever one of their representatives is convicted of the sale, purchase or trade, or offer to sell, purchase or trade a drug sample in violation of section 503(c)(1) or applicable state law. The Committee intends that this notification will trigger the proceedings to collect civil penalties outlined in section 7. The Secretary is expected to establish procedures for the prompt notification of the Department of Justice of all convictions and whether or not other such convictions have been obtained in the case of other representatives of the manufacturer or distributor over a rolling ten year period.

Section 503(d)(3)(F) requires that drug manufacturers and distributors keep the Secretary informed of the name and telephone number of the individual responsible for supplying information regarding drug samples.

SECTION 6—WHOLESALE DISTRIBUTORS

This section amends section 503 of FDCA by adding a new subsection 503(e). This provision is designed to restore accountability to the wholesale sector of the pharmaceutical market, and to regulate the wholesale distribution of prescription drug products.

The requirement in this section that wholesale distributors must inform their wholesale customers of all previous sales of the product applies only to wholesale distributors who are not authorized distributors for that product. Authorized distributors, as defined, are exempt from this requirement. Unauthorized distributors are those distributors who do not have an ongoing business relationship with a manufacturer to provide wholesale distribution of that manufacturer's products. Unauthorized distributors will be required to certify in writing to drug wholesalers the source and place from which they obtained their drugs. Manufacturers will be required to maintain, for public review, a current list of all authorized distributors of record.

Subparagraph 503(e)(2)(A) is intended to ensure that any person or firm engaging in the wholesale distribution of pharmaceuticals to any person or firm for resale shall be licensed in the state in which it does business and that the state licensing requirements meet certain minimum standards. The mere shipment of pharmaceuticals into a state would not trigger the requirement that the distributor be licensed in that state. However, the operation of a facility from which a wholesaler makes shipments outside the state would trigger the licensing requirement with respect to the state in which the facility is located.

Subparagraph 503(e)(2)(B) requires the Secretary of Health and Human Services to issue guidelines which will assure uniform standards covering the proper storage and handling of pharmaceuticals by wholesale distributors without regulatory duplication at the state and Federal levels.

SECTION 7—PENALTIES

This section amends Section 301 of the FDCA to add several prohibited acts to the statute [21 U.S.C. 331]. Section 301(t) would define the following as prohibited acts under the FDCA.

(1) the importation of a drug in violation of section 801(d)(1);

(2) the sale, purchase or trade, or offer to sell, purchase or trade a drug or drug sample in violation of 503(c);

(3) the sale, purchase, trade, or offer to sell, purchase or trade or the counterfeiting of a coupon as defined in section 503(c)(2);

(4) the distribution of a drug sample in violation of section 503(d), or failure to otherwise comply with section 503(d); or

(5) the failure to comply with the requirements of subsection 503(e).

Each of these newly prohibited acts is discussed in the applicable sections of this report.

This section also amends Section 303 of the FDCA [21 U.S.C. 333]. It combines subsections (a) and (b) into a single subsection and adds a new subsection (b). Subsection (b)(1) makes certain violations felonies by imposing penalties of imprisonment for not more than

ten years or fines of not more than $250,000 or both. These felony penalties apply to violations of section 301(t) because of an importation of a drug in violation of 801(d)(1) or because of a sale, purchase or trade, or offer to sell, purchase or trade of a drug or drug sample in violation of section 503(c), or because of the sale, purchase or trade, or offer to sell, purchase or trade, or counterfeiting of a coupon as specified in 503(c)(2), or because of the distribution of drugs by an unlicensed wholesaler in violation of section 503(e)(2)(A). Subsection (b)(2) provides civil penalties for drug manufacturers or distributors whose employees violate section 301(t) by buying, selling or trading, or offering to buy, sell or trade drug samples as prohibited by section 503(c)(1) or state laws which prohibit the purchase, sale or trade, or offer to purchase, sell or trade drug samples. The civil penalties can only be triggered by conviction of one or more representatives of a drug manufacturer or distributor in a Federal or state court.

In both section 5 and section 7, the Committee uses the term "representative" to describe the individual who may physically deliver drug samples for a manufacturer or distributor to a licensed practitioner. These individuals are most commonly described as representatives, sales representatives, salesmen, or detailmen. In this context, when using the term "representative," the Committee intends to include anyone who, for compensation or hire, makes drug sample distributions for a particular firm. It does not include the employees of common carriers.

Despite decades of abuse of drug samples by manufacturers' sales representatives, the Pharmaceutical Manufacturers Association argued strongly that it was possible for their member companies to adopt audit and security systems which would end the abuses. Acting on this assurance, the Committee decided to continue to permit manufacturers and distributors to physically dispense drug samples through their representatives and to provide for large civil penalties to be levied on those companies whose audit and security systems prove inadequate to prevent abuse. Subsection (b)(2) provides that for the first two convictions for unrelated violations of Federal or state law regarding the purchase, sale or trade, or offer to purchase, sell or trade drug samples by their representatives in any ten-year period, the manufacturer or distributor shall be liable for a civil fine of not more than $50,000 for each violation. However, for each violation by a representative or representatives of the manufacturer or distributor resulting in a conviction after the second conviction in any 10 year period, the manufacturer or distributor will be liable for a civil penalty of not more than $1 million.

It is not the intention of the Committee that the penalty provisions of this statute should be applied in a harsh and discriminatory way to smaller firms and businesses. By placing a one million dollar ceiling on the fines to be imposed, the Committee has obviously interposed a protection for the larger firms in this country which limits the impact of these fines. While the statute does not set out any sliding scale of fines which would afford the same degree of protection to smaller businesses, it should be clearly understood that an evenhanded application is desired. The fine imposed on a smaller company should not do proportionately more

damage to that company than the imposition of a one million dollar fine would do to the largest of companies.

For purposes of this subsection, multiple convictions of one or more persons arising out of the same event or transaction or a related series of events or transactions shall be considered as one violation.

Subsection (b)(3) creates a civil penalty of not more than $100,000 for any drug manufacturer or distributor who violates section 301(t) by failing to report to the Secretary any conviction of their representatives for violations of Section 503(c) or state law because of the sale, purchase or trade, or offer to sell, purchase or trade, a drug sample. This is an addition to any criminal liability which may attach to a manufacturer or distributor as a result of a failure to report such convictions in violation of section 301(t).

Subsection (b)(4)(A) absolves a drug manufacturer or distributor from civil liability for a particular violation by a representative of such manufacturer or distributor if the company itself provides the information leading to the arrest and conviction of such employee for a violation of section 301(t) because of a sale, purchase or trade, or the offer to sell, purchase or trade a drug sample in violation of section 503(c)(1) or for a violation of state law prohibiting the sale, purchase or trade, or offer to sell, purchase or trade a drug sample.

Subsection (b)(4)(B)(i) absolves a drug manufacturer or distributor from civil liability provided it shows by clear and convincing evidence that it was conducting a good faith investigation of the events or transactions which resulted in the arrest and conviction of one or more of its representatives for selling, purchasing or trading, or offering to sell, purchase or trade drug samples and that that investigation would have led to the reporting of information leading to the arrest and conviction of that employee or employees had not state or Federal law enforcement officials filed charges against the employee or employees before the manufacturer's or distributor's investigation could be sufficiently complete to merit referring the information to law enforcement authorities. The Committee intends that this defense apply only to active, credible internal investigations and not the mere accumulation of incriminating information in the company files. Of course, the company's history of cooperation with state and federal law enforcement and regulatory bodies, including its response to reasonable requests for records, would be a factor in the determination of whether a company's internal investigation was in good faith and would have led to a reporting of the necessary information.

Subsection (b)(4)(B)(ii) creates one additional exception to the civil liability of drug manufacturers or distributors whose representatives are caught abusing drug samples. It is included only to cover truly extraordinary circumstances in which a company is making a maximum effort to detect abuses of its sample distribution system but is still victimized by one of the representatives. The purpose of this exception is to require manufacturers to design and effectively implement an audit and security system that has a very high probability of detecting a violation. It creates a performance standard for such audit and security systems. They must be "designed to detect violations." The Committee intends a very strong presumption that if the systems fail to detect the abuse of samples by an

employee of a pharmaceutical manufacturer prior to the discovery by state or Federal law enforcement officials, then the audit and security system of that manufacturer is deficient and this defense would not be applicable.

Only in extremely rare cases would a company be able to assert that no audit and security system could be expected to detect aberrant behavior. For example, a new employee who had undergone a rigorous security check prior to hire is caught selling samples before the initial audit of his records could reasonably have been expected to occur, or an employee commits a violation because of mental incompetence. Even in such a case, the company would bear the burden of demonstrating by clear and convincing evidence that its audit and security systems would have detected the abuse of samples but for the extraordinary nature of the violation.

Moreover, any audit and security system sufficient to meet the "designed to detect" performance standard must be capable of detecting falsified or incomplete records.

A showing that the audit system was in line with the prevailing industry standard would, in itself, be insufficient to avoid liability under paragraph (ii). Rather, the company would be required to affirmatively demonstrate the scope and effectiveness of the audit and security system in detecting a broad range of potential violations.

Of course the audit and security system must include a mechanism for collecting data on sample distribution and the forwarding of this data at least monthly to appropriate security personnel. But the system cannot stop here. Specifically, the system must be designed to detect falsification of sample delivery forms of records. For example, a sales representative could alter a physician's request to reflect that he or she left twice the number of samples with a physician than was actually left, and sell or trade the excess. In this case, the inventory and distribution records for that sales representative would appear to be in balance. Thus, the audit system must go well beyond a mere reconciling of the books, and must include enough visits to recipient practitioners' offices on a timely enough basis so as to establish, in a statistically reliable number of cases, that the samples said to have been delivered to the practitioner's office by the sales representative were actually delivered. Further, the visits must be of sufficient frequency to establish in the minds of the sales force the reasonable probability that the employer will detect any abuses.

The Committee does not intend that the practitioner must personally give such verification, but only that a responsible person in the office, the receptionist, nurse, etc., do so. Nor does the Committee intend this section to require that a manufacturer or distributor inquire into the use of samples given to a practitioner by a sales representative, or in any other way intrude into the physician/patient relationship. Specifically, the Committee does not intend to impose upon a manufacturer or distributor any responsibility to investigate the practitioner recipient of samples. An effective system is one which verifies, as indicated above, the delivery of samples as reported by sales representatives.

Such visits must be done without the advance knowledge of the sales representatives or their supervisors. During visits to practi-

tioners' offices, auditors should also inquire if any samples, such as those whose expiration date has been reached, have been returned to the sales representative.

The operation of the audit system must also meet the test that it is performed by persons independent of the sales force. To do otherwise would be tantamount to letting the fox guard the chicken coop. System managers must also require immediate reporting of losses, thefts, and the receipt or knowledge of any offer to violate the provisions relating to sample distribution. While the audit system must be independent of the marketing function of a company, it is not required to be outside the company.

The Committee recognizes that there may be a number of methods of implementing an audit and security system which could meet the "designed to detect" performance standard and intends to allow flexibility in the type of system companies adopt. For instance, small companies may lack the personnel and financial resources of larger pharmaceutical companies that market nationally recognized brand name drugs and which have the capacity to conduct on-site audit visits to physicians' offices. The Committee would be loathe to recognize the use of an alternative security and audit system predicated only on the size of pharmaceutical companies; however, it does not wish to impose verification requirements which would create a material hardship or be beyond the means of small companies. For such companies the Committee believes that an enhanced record-keeping system with mail and telephone audit components would satisfy the "designed to detect" standard.

An example of the kind of audit system that would represent compliance for a small company is as follows:

Detail personnel would fill out a form with each delivery clearly indicating the date of the delivery, the number of units delivered and the specific drug involved. The form would be signed by the physician and mailed by the detail personnel to those individuals in the company charged with the responsibility of auditing the program, and the detail personnel would keep a copy of the forms for their own records.

An identical form would be left by the detail personnel with the practitioner's office to be filled out by the responsible person in the practitioner's office and mailed back to the company auditing personnel. A copy of the form would be maintained in the practitioner's office.

Company audit personnel would place calls to the practitioner's office with sufficient frequency to determine that the forms on file with the company auditor accurately reflected deliveries made to the practitioner.

The two characteristics of companies that the Committee regards as "small companies" are as follows: (1) the companies are small pharmaceutical businesses as recognized in federal regulations (e.g., Small Business Administration regulations at 13 CFR Part 121 (1987)); and (2) their samples are provided to physicians in small amounts (e.g., 18 to 24 solid dosage forms, 5 ounces liquid dosage forms).

By this, the Committee does not intend to create a loophole by which larger pharmaceutical companies may adopt less than effective audit and security procedures. Once a company attains a size

at which it no longer qualifies as a small business, it shall be held to the same standard as other companies with regard to its audit and security system; and pharmaceutical companies that are not small businesses as of the date of enactment of this legislation may not reorganize—for instance, by creating separate entities to engage in sales, distribution or manufacturing—in order to qualify as a small business.

In addition, the Committee wishes to make it clear that this special treatment for small businesses is only to apply to audit and security systems established pursuant to this legislation, and does not establish any precedent for distinguishing between small and large firms under other provisions of the Federal Food, Drug and Cosmetic Act.

The Committee recognizes that any audit can work only with the voluntary cooperation of the physicians involved, who, under the terms of this legislation, are not required to maintain records on drug sampling. While pharmaceutical companies may be unable to persuade some of their physician customers to comply with the audit procedure, the companies are nonetheless expected to devise effective systems for detecting abuses of their sample distribution systems.

Finally, the ability to demonstrate that a conviction by a representative under this subparagraph should not count toward the civil penalty provisions is not available in convictions involving supervisory personnel. It is one thing to argue that the company should not be penalized because of the unpredictable behavior of its lower level employees, in this case, sales representatives. But it is quite another to contend that the actions of supervisors, who occupy positions reflecting an enhanced level of trust and responsibility, should not affect the company.

Subsection (b)(5) provides that any person providing information leading to the arrest and conviction of a person for the purchase, sale or trade, or the offer to purchase, sell or trade a drug sample shall be entitled to one-half of the criminal fine collected, up to a maximum of $125,000.

SECTION 8—EFFECTIVE DATE

With several exceptions, all provisions of the legislation take effect 90 days after the date of enactment. One exception is that the Secretary is required to issue guidelines within 180 days of enactment under 503(e)(2)(B) that establish minimum standards, terms and conditions for the licensing by the states of wholesale distributors that engage in interstate commerce. Further, the requirement in 503(e)(2)(A) that wholesale distributors that engage in interstate commerce be licensed by a state in accordance with the minimum standards issued by the Secretary does not take effect until two years after the effective date of the regulations.

The requirements for the distribution of sample drugs continued in section 503(d) do not take effect until 180 days after enactment.

IV. Vote of the Committee in Reporting the Bill

In compliance with section 133 of the Legislative Reorganization Act of 1946, the Committee states that the bill was ordered favorably reported by voice vote.

V. Budgetary Impact of the Bill

In compliance with sections 308 and 403 of the Congressional Budget Act of 1974 and paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the Committee received the following report of the Congressional Budget Office under section 403 of the Congressional Budget Act:

U.S. Congress,
Congressional Budget Office,
Washington, DC, December 14, 1987.

Hon. Lloyd Bentsen,
Chairman, Committee on Finance,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed H.R. 1207, the Prescription Drug Marketing Act of 1987, as ordered reported by the Senate Committee on Finance on December 11, 1987. Enactment of this bill could result in increased costs to the federal government of up to $1 million in each year. The budgets of state and local governments would not be affected directly by the enactment of this legislation.

H.R. 1207 would place restrictions on the reimportation of prescription drugs. It would make the sale, purchase or trade of prescription drug samples illegal and place new restrictions on the distribution of samples. Most of the costs associated with the new requirements established by the bill would be incurred by prescription drug manufacturers. The Food and Drug Administration (FDA) would be responsible for issuing guidelines for the licensing of wholesale distributors and approving proposed sample request forms. FDA would also be the agency notified in the case of theft, diversion or loss of prescription drug samples.

FDA would have enforcement authority, as they currently have over all aspects of the Food, Drug, and Cosmetic Act. It is not clear, however, how FDA might choose to enforce this legislation. H.R. 1207 could require FDA to conduct more extensive reviews of manufacturers' drug import records and of physicians' sample distribution records. Enforcement could also include surveillance of hospitals and other health care facilities.

FDA has estimated that a similar bill introduced last year could result in increased workloads requiring an additional 30 full-time equivalents at a cost of $1.5 million each year. Based on the FDA estimate, CBO expects enactment of H.R. 1207 would result in additional costs of about $1 million in each fiscal year, because FDA has already devoted some additional personnel to monitoring reimported American goods. Actual costs would depend largely on the level of enforcement activities undertaken by the agency and the extent to which FDA would expand to accommodate the increased workload.

Please call me or have your staff contact Carmela Dyer if you have any questions.

With best wishes,

Sincerely,

EDWARD M. GRAMLICH,
Acting Director.

VI. REGULATORY IMPACT OF THE BILL

Pursuant to Rule XXVI, paragraph 11(b), of the Standing Rules of the Senate, the Committee makes the following statement relative to the regulatory impact of H.R. 1207. The bill imposes new regulatory requirements that will affect all manufacturers, wholesalers, and, to an extent, retailers of prescription pharmaceuticals. While a precise estimate of the cost of these regulations to the affected businesses cannot be made, the Committee notes that the cost will likely be offset by savings to the industry as a result of the sections banning reimportation and resales by health care institutions.

The Committee states that the bill will have no impact on the personal privacy of any individual. With regard to the impact of this bill on the amount of additional paperwork and recordkeeping that will be required, the Committee notes that section 5 of the bill requires manufacturers and distributors of prescription drugs who distribute drug samples to physicians to maintain copies of sample request forms, receipts and other pertinent documentation for a period of three years and to make the documents available for inspection by Federal and state officials.

VII. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill H.R. 1207, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER III—PROHIBITED ACTS AND PENALTIES

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PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

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(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, pur-

chase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e).

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PENALTIES

SEC. 303. (a) *(1)* Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

[(b)] *(2)* Notwithstanding the provisions of [subsection (a)] *paragraph (1)* of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) because of an importation of a drug in violation of section 801(d)(1), because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), or the distribution of drugs in violation of section 503(e)(2)(A) shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to

the arrest and conviction of any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the arrest of such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the arrest and conviction of such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the arrest and conviction of a person for a violation of section 301(t) because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1), such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) * * *

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(c)(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer of distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with section 503(b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b), and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with section 503(b).

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d)(1) Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer or distributor may distribute any drug sample.

(2)(A) The manufacturer or distributor of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or distributor.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or distributor which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or distributor to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or distributor of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or distributors shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or distributors shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. Drug manufacturers or distributors shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or distributors shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subparagraph, of all thefts, or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or distributor to the Secretary upon request.

(D) Drug manufacturers or distributors shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or distributors shall report to the Secretary any conviction of their representatives for violations of section 503(c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or distributors shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(e)(1) Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B).

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CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) * * *

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(d)(1) Except as provided in paragraph (2), no drug subject to section 503(b) which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the person who manufactured the drug.

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

[(d)]*(e)*(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 514 or 515.

(B) which under section 520(g) is exempt either such section, or

(C) which is a banned device under section 516,

unless, in addition to the requirements of paragraph (1), the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.

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